MAR 0 1 2013

Section 5: 510 (k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93)

Submitter Information	
Name	DePuy Orthopaedics, Inc.
Address	700 Orthopaedic Drive, Warsaw, Indiana 46582
Phone number	(574) 371-4981
Fax number	(574) 371-4987
Establishment Registration Number	1818910
Name of contact person	Correne Ramy
Date prepared	February 25, 2013
Name of device	
Trade or proprietary name	DePuy Gription® TF 5.5mm Sterile Locking Screws
Common or usual name	5.5mm Sterile Locking Screws
Classification name	Hip joint metal/polymer/metal, semi-constrained, porous-coated, uncemented prosthesis Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis Hip joint metal/polymer, semi-constrained cemented prosthesis
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3358, 888.3353, and 888.3350
Product Code(s)	LPH, LZO, JDI
Legally marketed device(s) to which equivalence is claimed	DePuy Universal Gription TF Acetabular Augment System (K100391, cleared September 29, 2010)
Reason for 510(k) submission	Line extension
Device description	The subject devices represent sterile screws with additional lengths to allow surgeons more flexibility for the fixation of the acetabular augments, buttresses, and shims. Specifically, the lengths include 14-24mm in increments of 2mm and lengths 25-70mm in increments of 5mm.

Intended use of the device	Total hip arthroplasty
Indications for use	Total hip replacement is indicated in the following conditions: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia. 2. Avascular necrosis of the femoral head. 3. Acute traumatic fracture of the femoral head or neck. 4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement. 5. Certain cases of ankylosis. The porous Gription TF titanium acetabular augment is affixed to the mating acetabular cup using bone cement or mechanical screw fixation. The assembled augment/acetabular cup construct is intended for cemented or cementless use. The porous Gription TF titanium shim is affixed to the mating buttress using bone cement. This porous Gription TF titanium buttress is affixed to the mating acetabular cup using bone cement. The Gription TF titanium buttress/shim is affixed to the bone using bone cement or mechanical screw fixation. The assembled buttress/acetabular cup construct is intended for cemented or cementless use.

Summary of the technological characteristics of the device compared to the predicate device

Characteristic	DePuy Gription® TF 5.5mm Sterile Locking Screws	DePuy Universal Gription TF Cones and Acetabular Augment System 5.5mm Cancellous Locking, Non-Sterile Screws [Comparable Screws] (K100391)
Material	TI-6AL-4V-ELI	TI-6AL-4V-ELI
Head geometry	Locking	Locking
Lengths	14-24mm in 2mm increments 25-70mm in 5mm increments	25-100mm in 5mm increments
Major diameter	5.5mm	5.5mm
Sterility	Sterile	Non-Sterile
Method of Sterilization	Gamma radiation	None

PERFORMANCE DATA
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE
Print review, tolerance analysis, and push out testing of subject device screws
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
No clinical testing was required to demonstrate substantial equivalence.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The results of the non-clinical testing support substantial equivalence of the subject device to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 1, 2013

DePuy Orthopaedics
% Ms. Correne Ramy
Regulatory Affairs Associate
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K123924
Trade/Device Name: DePuy Gription® TF 5.5mm Sterile Locking Screws
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, JDI, LPH
Dated: December 19, 2012
Received: December 20, 2012

Dear Ms. Ramy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510 (k) Number (if known): K123924

Device Name: DePuy Gription® TF 5.5mm Sterile Locking Screws

Indications for Use:

The DePuy Gription TF Acetabular Augments, Buttresses and Shims are indicated for use with the Pinnacle® Acetabular cup System, the Pinnacle® Bantam Acetabular Cup System and the Pinnacle® Revision Acetabular Cup System for total hip replacement in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The porous Gription TF titanium acetabular augment is affixed to the mating acetabular cup using bone cement or mechanical screw fixation. The assembled augment/acetabular cup construct is intended for cemented or cementless use.

The porous Gription TF titanium shim is affixed to the mating buttress using bone cement. This porous Gription TF titanium buttress is affixed to the mating acetabular cup using bone cement. The Gription TF titanium buttress/shim is affixed to the bone using bone cement or mechanical screw fixation. The assembled buttress/acetabular cup construct is intended for cemented or cementless use.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices